

Kelly A. Booth, M.D.,

Page 1

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP., MDL NO. 2326  
PELVIC REPAIR SYSTEM  
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO  
HANNA WILKERSON,  
Plaintiffs,

vs.

BOSTON SCIENTIFIC  
CORPORATION,

Defendant.

Case No.  
2:13-cv-4505

Videotaped Deposition of Kelly A. Booth, M.D.  
Thursday, November 13, 2014  
Huntersville, North Carolina  
At 12:35 p.m.

Reported By: LeShaunda D. Cass-Byrd, CSR, RPR

Golkow Technologies, Inc.  
877.370.3377ph|917.591.5672 fax  
Deps@golkow.com

EXHIBIT

C

Kelly A. Booth, M.D.,

Page 19

1 the day or where the Depends pads or something like  
2 that for incontinence or severity of bulge and  
3 pressure discomfort, there is a different level of  
4 tolerance, depending on the individual patient. So  
5 how to parse out whether the patient is leaning  
6 towards a surgical plan versus a medical plan, is has  
7 a lot to do with what the individual desires.

8 Q. And if -- if a patient appears to be a  
9 surgical candidate, what are some of the options that  
10 you would offer to her?

11 A. Well, the standard of care is -- for  
12 urinary incontinence is a tension-free vaginal tape.  
13 In patients that have no symptoms, and you find on  
14 exam -- you just so happen to find the laxity of the  
15 bladder, the posterior compartment, or at the apex  
16 some decent. And they are not having symptoms, you  
17 don't -- you don't -- you may say, "Oh, you might --  
18 your bladder is falling just a little bit." But you  
19 don't move towards offering them any kind of surgical  
20 management if they are not systematic.

21 But from the standpoint of urinary  
22 incontinence, the gold standard is -- now, it can just  
23 be vaginal tape. And I came along in the days of  
24 using a Burch procedure retropubic sling. Did Burch  
25 procedures laparoscopically and open -- for the most

Kelly A. Booth, M.D.,

Page 20

1 part, open -- at Duke.

2 And when I came here, continued to do them  
3 until it was an accepted and gold standard  
4 literature-proven way to decrease complications and  
5 improve outcomes, long term, by using the tension-free  
6 tape.

7 Now, for years, the urologists had been  
8 doing slings and whatnot. But they were not doing  
9 them tension free, and so the outcomes for retention  
10 and all were very high. So it was something that we  
11 kind of watched and waited until good data came out.

12 And as it became accepted gold standard,  
13 then the tension-free tape surpassed the -- the Burch  
14 procedure as the recommended standard of care by our  
15 college, ACOG. So...

16 Q. And is that still true today?

17 A. Yes.

18 Q. When you use the term "tension-free vaginal  
19 tape," is that a generic term that encompasses  
20 different brands?

21 A. Yes.

22 Q. And would the Advantage Fit fall within  
23 that description?

24 A. Yes.

25 Q. Let me go back a little bit to your

Kelly A. Booth, M.D.,

Page 36

1 but -- but do not have urinary incontinence from  
2 detachment of the urethra or a drainpipe or ISD  
3 urethra, intrinsic sphincteric deficiency.

4 So urodynamics do a wonderful job of  
5 teasing that out, to be certain that we are not  
6 providing a surgical option for somebody that would be  
7 better served with a medical option.

8 Q. Okay. And we will talk about the  
9 urodynamics in a minute. But finishing out this  
10 record, you wrote, She needs anterior compartment  
11 repair. What do you mean by that?

12 A. An anterior repair. Basically, anterior  
13 colporrhaphy, which is to plicate the fascial tissue.  
14 Almost like the repair of a hernia on the abdominal  
15 wall, to basically bring the strong tissue together  
16 and reduce the hernia back where it belongs.

17 Q. And it looks like you discussed with her  
18 that -- the repair that you thought that she would  
19 likely need and the tension-free vaginal tape, but you  
20 wanted her to go to get the urodynamics first; is that  
21 correct?

22 A. Right.

23 Q. You noted that you spent 45 minutes  
24 face-to-face time with the patient, greater than 40  
25 percent of that in counselling and coordination of



Kelly A. Booth, M.D.,

Page 37

1 care. Does that mean that you spent greater than 50  
2 percent of that time actually talking with  
3 Ms. Wilkerson?

4 A. Yes.

5 Q. And in the conversation that you had with  
6 her, did you explain the interior repair and the use  
7 of the tension-free vaginal tape?

8 A. We talked about that. And we talked about  
9 why I thought the -- usually would discuss why I  
10 thought that the leakage got better with time, just to  
11 sort of explain the physiology of why she noticed the  
12 bulge get worse but the leakage got better. Because  
13 that is confusing to patients.

14 And then they say, "Well, why do you want  
15 to fix the incontinence if I'm not having an  
16 incontinence problem?"

17 So -- and I -- you know, I think I probably  
18 introduced that idea of a TVT, but wanted to go into  
19 greater detail with her about that at a later time.  
20 We -- since it's been a while and I don't have every  
21 detail of what was discussed -- but I imagine that is  
22 what I did.

23 Q. That would have been consistent with your  
24 usual practice?

25 A. Absolutely.

Kelly A. Booth, M.D.,

Page 39

1 integrity.

2           So we eliminate the suspicion for intrinsic  
3 sphincteric deficiency if the integrity of the urethra  
4 is good. But with the finding of the leak with  
5 Valsalva at 300 cc's, that is consistent with genuine  
6 urinary stress incontinence -- or stress urinary  
7 incontinence, but without a intrinsic sphincteric  
8 deficiency component. So that basically indicates  
9 that the leakage was just caused by detachment of the  
10 urethra from the fascia.

11           So to -- to assist with that, once --  
12 reducing that hernia, repairing that cystocele with an  
13 anterior repair, if we left it at that, we would end  
14 up with leakage. So doing that would be doing her  
15 dis- -- a disservice. And I think then we -- when I  
16 got these results, we discussed what would need to be  
17 done to -- to assist with that.

18           Q.       So is it fair to say that the urodynamics  
19 confirm what you suspected on your exam --

20           A.       Uh-huh (affirmative).

21           Q.       -- you expected to find this?

22           A.       Yes.

23           Q.       And confirmed your -- your preliminary plan  
24 to do the anterior repair and use the TVT to support  
25 her urethra?

Kelly A. Booth, M.D.,

Page 40

1 A. Yes.

2 Q. Okay. And then she came back to see you on  
3 February 12th, 2010?

4 A. Yes.

5 Q. And --

6 A. To discuss the urodynamics.

7 Q. -- and it looks like you spent the entire  
8 visit in discussion with her rather than performing  
9 any exams; is that correct?

10 A. Right.

11 Q. Because you wanted to spend some time doing  
12 a detailed discussion of the surgical management that  
13 were you proposing?

14 A. Right.

15 Q. And did you explain to her what you've just  
16 explained to us about why she was not having leakage  
17 but still needed a repair to the -- to the urethra --

18 A. Yes.

19 Q. -- or support?

20 A. Yes. Yes.

21 Q. Do you remember Mrs. Wilkerson specifically  
22 or --

23 A. Uh-huh (affirmative).

24 Q. -- are you relying on your records?

25 You remember her?

Kelly A. Booth, M.D.,

Page 41

1 A. Yeah, I do.

2 Q. And under your plan you recorded that you  
3 were going to proceed with the anterior repair and the  
4 TVT and cystopathy. We haven't talked about  
5 cystopathy. What does that mean?

6 A. Cystopathy is performed after any anterior  
7 repair and/or tension-free tape, in my practice. And  
8 really, probably likely, the majority of GYNs, to  
9 confirm that there is no injury to the urethra or the  
10 ureters or the bladder itself. Because you are  
11 operating basically in close proximity to all of the  
12 structures of the bladder.

13 And cystopathy is performed at the  
14 completion of both procedures to confirm that there is  
15 no harm to those organs -- or that organ and the  
16 ureters.

17 It is performed by taking a lighted scope  
18 into the bladder and instilling normal saline into the  
19 bladder -- or sterile water -- to look around and make  
20 sure that there is no evidence of the sutures that you  
21 have used to repair the prolapse or the tension-free  
22 tape that you have used to secure the urethra into its  
23 normal and natural angle.

24 And the way that the tension-free tape that  
25 I typically use, the way that that is easy to discern



Kelly A. Booth, M.D.,

Page 42

1 is by looking laterally with a 70 degree cystoscope to  
2 see if there is any evidence of the introducer.

3 So when the procedure is performed, the  
4 introducer is basically left -- left there before the  
5 cystopathy is complete, to confirm that there is no  
6 mal placement of the tape. And the tape itself is  
7 contained within this introducer, which is a bright  
8 blue color in the Advantage Fit device.

9 And if you look laterally on each side of  
10 the bladder, you will not see the -- the blue color  
11 and you will know that you are not -- you have not  
12 penetrated or perforated the bladder with the tape.

13 And then at that point, the introducer can  
14 be removed. So we -- you know, we -- we can  
15 fast-forward to the procedure. Or I will wait for  
16 your question.

17 Q. Okay. We will get there. I just want to  
18 finish going over what you discussed with her.

19 A. Uh-huh (affirmative).

20 Q. You documented that you reviewed with the  
21 patient the risks of bleeding, infection, damage to  
22 surrounding organs, including bladder, bowels and  
23 ureters. Is that something that you routinely do?

24 A. Yes.

25 Q. And did with Ms. Wilkerson?

Kelly A. Booth, M.D.,

Page 43

1 A. Yes.

2 Q. And you also discussed with her -- with her  
3 the risk of a possible recurrence of her stress  
4 incontinence.

5 A. Yes.

6 Q. And recurrence of her prolapse.

7 A. Uh-huh (affirmative).

8 Q. And mesh erosion. What do you mean by  
9 that?

10 A. Mesh erosion is when the tape, the  
11 tension-free tapes that are on the market are  
12 basically seen as a foreign body by the -- by the  
13 vagina. And in some cases, they can be extruded  
14 through the vagina and cause irritation, discomfort  
15 with intercourse, vaginal discharge, some spotting or  
16 bleeding.

17 And if that is to happen, it is something  
18 that we talk about how it would be managed  
19 postoperatively, if that were to happen. And also  
20 talk about the fact that it -- that could happen  
21 remote from the time of -- of the procedure, and what  
22 to watch out for symptom-wise if it were to happen.

23 And so we discussed that in great detail.  
24 The -- I do discuss that the mesh, in the case of the  
25 TVT, is a very limited site in the vagina where there

Kelly A. Booth, M.D.,

Page 44

1 is not a whole lot of area for the mesh to erode or  
2 protrude and cause a problem.

3 So that if -- if it were to happen, we  
4 discuss if -- that it might require another procedure,  
5 either in the office or in the hospital, to help  
6 either remove or just advance vagina over the mesh,  
7 because it can be irritating.

8 Now, mesh erosion into the bladder is not  
9 something that I have seen in the practice of using a  
10 TVT and placing it properly, if the -- if the  
11 cystopathy is negative.

12 So I suppose that erosion into the bladder  
13 is something that is reported in cases. But we  
14 discuss mesh erosion related to the vagina because  
15 that is the most common circumstance. And that -- as  
16 far as which way mesh would erode -- erode.

17 So anybody that is going to have placement  
18 of a foreign body, a tension-free tape or  
19 sacrocolpopexy, will be counseled on vaginal mesh --  
20 mesh erosions and what the symptoms are of that so  
21 they can watch out for it.

22 Q. So that is something you went over with Ms.  
23 Wilkerson?

24 A. Yes.

25 Q. And in the cases that you have you seen of

Kelly A. Booth, M.D.,

Page 45

1 mesh erosion, has that been something that you can  
2 sometimes simply treat on outpatient basis?

3 A. Yes. Many of the cases respond well to  
4 just vaginal estrogen cream, which causes advancement  
5 of healthy mucosa.

6 Q. And you also discussed with her the  
7 possible risk of urinary retention as well?

8 A. Yes.

9 Q. And then you documented that knowing these  
10 risks, the patient was willing to proceed and that you  
11 answered her questions?

12 A. Yes.

13 Q. Okay. And that you spent 30 minutes  
14 face-to-face time with her, was greater than 50  
15 percent of the time in counseling and coordinating?

16 A. Yes.

17 Q. So when you finished explaining these risks  
18 to Ms. Wilkerson, you had informed her that she could  
19 have a recurrence of both her prolapse and her stress  
20 urinary incontinence. You had explained that to her?

21 A. Yes. Yes.

22 Q. And -- and as far as you can tell, she  
23 understood that?

24 A. Oh, yes. Uh-huh (affirmative).

25 Q. And I don't think this is in your chart.



Kelly A. Booth, M.D.,

Page 46

1 Let me just show you the consent form.

2 (Booth Exhibit 3 was marked for  
3 identification.)

4 BY MS. PACKER:

5 Q. Which comes from the hospital chart. And I  
6 apologize for the poor copy.

7 A. Oh, it looks pretty good to me. I have  
8 seen worse.

9 Q. So -- so -- so have we.

10 Is this a consent form that you or somebody  
11 operating under your supervision or working under your  
12 supervision had Ms. Wilkerson sign?

13 A. Yes.

14 Q. And who would have gone over this with her.  
15 Do you know?

16 A. Myself, and Susan Hales, who is our, at  
17 that time, posting folks for surgery.

18 Q. And so the signature at the bottom where it  
19 says physician is your signature?

20 A. Yes.

21 Q. Okay. So you went over with this in  
22 addition to Susan?

23 A. Yes.

24 Q. And if she had had any questions, you would  
25 have answered them?

Kelly A. Booth, M.D.,

Page 47

1 A. Yes.

2 Q. And then you asked the patient to sign and  
3 initial on the bottom left; is that correct?

4 A. Yes.

5 Q. Okay. Let's go now to the next thing that  
6 happened, which I believe would have been the  
7 procedure itself.

8 A. Okay.

9 Q. Do you have that note?

10 A. I do.

11 Q. And it looks like the -- the date of the  
12 operation was March 9th, 2010.

13 A. That is correct.

14 Q. And so the consent form would have been  
15 signed in your office on a prior preop visit?

16 A. Right.

17 Q. Okay.

18 A. Which was February 12th, 2010.

19 Q. Okay. So referring to your operative note,  
20 can you walk us through the procedure that you  
21 performed?

22 A. Sure. The preoperative diagnosis is stress  
23 urinary incontinence and a cystocele. The procedures  
24 described are tension-free vaginal tape cystopathy and  
25 anterior colporrhaphy, also known as an anterior

Kelly A. Booth, M.D.,

Page 49

1 Q. -- so where it says dilation, it should say  
2 violation.

3 A. Uh-huh (affirmative).

4 Q. Okay.

5 A. So then --

6 Q. Let me stop you before you get any further.  
7 Under description of the procedure it says:  
8 Following detailed informed consent. Did you review  
9 the informed consent again before the surgery?

10 A. Yes. In the preoperative area, just to  
11 make sure there is no further questions, oftentimes  
12 with the significant other, if they were not able to  
13 be there at the signing of the consent form in the  
14 office. That's just a standard of care, and we do  
15 that with every single case -- or I do that with every  
16 single case. And it's actually required by the  
17 hospital as well.

18 Q. And would that discussion immediately prior  
19 to surgery include a review of the potential risks and  
20 complications, as you went over in your office before?

21 A. Yes. And answer any questions related to  
22 those risks.

23 Q. Okay. You can go ahead and just walk us  
24 through the procedure, if you would.

25 A. So following detailed informed consent, the

Kelly A. Booth, M.D.,

Page 50

1 patient was taken in the operating room and placed in  
2 the dorsal lithotomy position. And after successful  
3 general anesthesia was achieved, the patient was  
4 placed in the Allen stirrups and sterilely prepped  
5 vaginally and perineally, and draped in the usual  
6 fashion.

7 In-and-out catheterization of the bladder  
8 was performed and the weighted speculum was inserted  
9 into the vagina.

10 The vaginal apex was grasped with Alex --  
11 Allis clamps, and the cystocele was isolated and  
12 evaluated. Approximately 20 cc's or ml's of 1 percent  
13 lidocaine with one and 200 concentration of  
14 epinephrine was injected to the vaginal mucosa.

15 The vaginal mucosa was thin in size in the  
16 midline, and the mucosa was dissected off the  
17 underlying paravascular fascia using sharp dissection  
18 with the Stroli scissors.

19 The midline defect was identified and a  
20 series of interrupted imbricating sutures of 2-0  
21 Vicryl were placed to plicate the perivascular fascia  
22 in the midline.

23 The vaginal mucosa was then trimmed and  
24 reapproximated, using 3-0 Vicryl in a running, walking  
25 fashion. Through a separate incision in the



Kelly A. Booth, M.D.,

Page 51

1 mid-urethral area, the TVT mesh was introduced.

2           Once again, 1 percent lidocaine was  
3 injected into the vaginal mucosa, and half percent  
4 Marcaine injected to the space of Retzius at the sites  
5 where trocars were to be placed.

6           These sites were marked, two-fingerbreadths  
7 lateral to the midline, over the pubic symphysis.

8           The vaginal mucosa was undermined to the  
9 urogenital diaphragm. And using the Strolzi scissors  
10 in the Boston Scientific -- it says Align Fit, but  
11 it's supposed to be Advantage Fit --

12         Q.       Okay.

13         A.       -- was assembled and placed through the  
14 urogenital diaphragm. The patient right -- it says  
15 fifth trocar -- but right trocar was then directed to  
16 the isolateral shoulder on the right side and exited  
17 through the appropriate demarcation at the level of  
18 pubic symphysis.

19           In a similar fashion, the trocar was  
20 introduced through the patient's left urogenital  
21 diaphragm. And directing towards the -- the trocar  
22 towards the demarcated site on the left pubic  
23 symphysis, directing towards the lateral shoulder on  
24 the left.

25           This trocar was introduced through the

Kelly A. Booth, M.D.,

Page 52

1 demarcated site. One amp of indigo carmine had been  
2 introduced by anesthesia and cystoscopy was performed  
3 to evaluate for any evidence of bladder injury. Both  
4 ureteral orifices were spilling indigo carmine-tinged  
5 urine vigorously.

6           The Mayo scissors were placed beneath the  
7 urethra as the mesh was drawn through the face of  
8 Retzius and trimmed in order to allow no tension to be  
9 placed on the mesh.

10           The vaginal mucosa was reapproximated over  
11 the mesh, using a horizontal imbricating suture of 40  
12 VICRYL. Vaginal packing with Premarin cream was  
13 placed and a Foley catheter was placed to straight  
14 drain.

15           Of note, while the trocars were being  
16 directed on both right and left side, the bladder was  
17 deviated to the opposite side using the catheter guide  
18 sheets in a Foley. This maneuver was performed in  
19 order to protect the bladder from injury.

20           At the completion of the case, all sponge,  
21 needle, and instrument counts were correct times two  
22 and the patient was awakened, excavated and taken to a  
23 recovery room, alert and in stable condition.

24           Q. Did this operation proceed without any  
25 complications?

Kelly A. Booth, M.D.,

Page 77

1 Q. Okay.

2 A. I think that is so that she could get  
3 breaks from her work to go to the office and do what  
4 she needed to do. Because frequently, when you do  
5 have a pessary in place, you have to come back at  
6 intervals of 10 to 12 weeks for removal, cleaning and  
7 replacement of the pessary. So it adds, you know, a  
8 time commitment.

9 Q. Right. Do you believe that Ms. Wilkerson  
10 was an appropriate candidate for this surgery that you  
11 performed?

12 A. Yes.

13 Q. Including the TVT portion of the surgery?

14 A. Yes.

15 Q. And based on the last time that you saw her  
16 and based upon the review the records of your  
17 practice, do you believe that she was harmed in any  
18 way by the mesh itself?

19 MR. CANTRELL: Object to the form.

20 BY MS. PACKER:

21 Q. He is objecting for the record, but you can  
22 answer.

23 A. Okay. I do not believe that she was harmed  
24 by the mesh at all.

25 Q. And the complication that she did have was

Kelly A. Booth, M.D.,

Page 83

1     reputable resources to review before they decide to go  
2     through with a TVT.

3             Now I don't offer the mesh kit repair,  
4     along with the rest of my partners. So...

5             Q.     With respect to the TVT repair, in your  
6     experience, what has been your complication rate?

7             A.     Oh, extremely low. The only -- I have not  
8     had any bladder injuries or urethral injuries. The  
9     complaints of mesh erosion are numbering three or  
10    four. I'm trying to -- one was actually the same  
11    patient. So I would consider that four. But it's  
12    three patients. But the erosion -- an erosion  
13    occurred the second time on somebody that was very  
14    atrophic in the vagina.

15            And as far as discomfort or pain,  
16    recurrence of incontinence, it's been a -- a joy of a  
17    procedure to perform, from the standpoint of minimal  
18    complications and very -- so much better recovery than  
19    a Burch procedure. So it's been good, all-around  
20    outcomes.

21            Q.     It's still a procedure that you perform on  
22    patients today?

23            A.     Yes. Yes. And would advise a family  
24    member to receive or -- yeah, absolutely.

25                    (Booth Exhibit 6 was marked for



Kelly A. Booth, M.D.,

Page 84

1 identification.)

2 BY MS. PACKER:

3 Q. Okay. Let me show you what I have marked  
4 as Exhibit 6, which is the directions for use -- make  
5 sure I don't give you my highlighted copy -- the  
6 directions for the Advantage Fit. Is that a document  
7 that you reviewed at some point in the past?

8 A. Yes.

9 Q. I assume it's not something --

10 A. Prior to use.

11 Q. -- you review every time. But --

12 A. No.

13 Q. -- but when you first started using the  
14 product?

15 A. Yes.

16 Q. And let me ask you, if you would, to turn  
17 to the third page of the document. Actually, the  
18 fourth page, where it says, Adverse events.

19 A. Okay.

20 Q. Are -- and I will give you a second to read  
21 it. But are the adverse events that are listed here  
22 all potential adverse events or complications that you  
23 were aware of through your general knowledge as a  
24 physician?

25 A. Yes.

Kelly A. Booth, M.D.,

Page 85

1 Q. So certainly you knew, from your own  
2 experience, that there were potential risks of a -- a  
3 pain or of failure of the procedure?

4 A. Yes.

5 Q. Okay. Thank you.

6 In making the decision about what of -- I'm  
7 moving away from that document now, Doctor.

8 A. Okay.

9 Q. In making a decision about whether you are  
10 going to use a medical device or not in your patients,  
11 we have already discussed CME training that you  
12 received, literature, confirming with your colleagues.  
13 Are there any other sources of information that you  
14 would typically rely on in making a decision that I am  
15 or am not going to use that particular medical device?

16 A. I can't think of anything other than that.  
17 I mean, conferences, like SGS, the Society for  
18 Gynecologic Surgeons, would be an additional -- you  
19 know, reputable conferences. And that is about all I  
20 can think of.

21 Q. There has been some testimony in -- in this  
22 mesh litigation, generally about materials safety data  
23 sheet for the raw material that was used to make some  
24 of the mesh. Is that a type of document that you are  
25 familiar with?

Kelly A. Booth, M.D.,

Page 94

1 something material to you.

2 MS. PACKER: Objection to the form.

3 BY MR. CANTRELL:

4 Q. Is that fair?

5 A. That I could investigate it. Okay.

6 Q. Okay. And you mentioned that -- a little  
7 bit earlier, about the FDA approval of these devices.  
8 And I -- I think you mentioned you just -- you got  
9 some general knowledge about that process; is that  
10 fair?

11 A. Yes.

12 Q. Okay.

13 A. Enough knowledge to know the FDA fully  
14 authorized the TVT application. And then the other  
15 mesh-kit type things seem to sort of grandfather under  
16 that policy. But, you know, mostly, if I'm going to  
17 use something that is an implantable device, I want to  
18 make sure that it's FDA approved.

19 Q. All right. Would you be surprised to learn  
20 that there were no premarket clinical trials on the  
21 Advantage Fit before its release?

22 MS. PACKER: Objection.

23 THE WITNESS: No, I wouldn't be.

24 Because if it's a similar mesh, then -- you  
25 know, in other words, mesh makeup, et

Kelly A. Booth, M.D.,

Page 95

1           cetera, I would not be surprised by that.  
2           Because at the first company that came out  
3           with it I believe was Johnson & Johnson,  
4           and most of the testing was probably done  
5           on the Gynecare products, which basically  
6           contain a similar -- similar fabric. So...

7 BY MR. CANTRELL:

8           Q.       Okay. Would it change your opinion to  
9           learn that the first product on the market was  
10          actually -- the first sling on the market was actually  
11          a protogen, which was manufactured by Boston  
12          Scientific, and was actually recalled from the market?

13                 MS. PACKER: Objection.

14 BY MR. CANTRELL:

15          Q.       Would that change your opinion, with that  
16          knowledge in mind?

17          A.       No. If it was recalled, it -- you know,  
18          no.

19          Q.       Okay. Fair enough.

20          A.       If I want to ask a question should it go  
21          off the record?

22                 MR. CANTRELL: Probably so. Yeah.

23                 THE WITNESS: Okay.

24                 MR. CANTRELL: Yeah. Do you want to  
25          take a quick break?



Kelly A. Booth, M.D.,

Page 99

1 the FDA's inquiry, provided by a compatibility data,  
2 would that be reassuring to you as a physician?

3 A. Yes.

4 Q. Would you rely on the FDA to make the  
5 ultimate decision about approval of this device,  
6 having considered the material safety data sheet and  
7 Boston Scientific data as supplied to the FDA?

8 A. Yes, that I would trust the FDA --

9 Q. And --

10 A. -- for that information.

11 Q. And in your decision-making process as a  
12 physician, you would rely on the FDA and you would  
13 also rely on -- as you've used the term --  
14 evidence-based literature?

15 A. Yes.

16 Q. And not on a -- one document that is a  
17 manufacturing-related document; is that fair to say?

18 A. Yes. I would be just a little skeptical.  
19 Not -- I mean, just because it's almost like one  
20 little disclaimer. And as I look at -- I don't know.  
21 I mean, I -- I would definitely rely more on a body of  
22 literature to tell me what outcomes were, then a -- a  
23 disclaimer to basically throw the baby out with the  
24 bath water, so to speak, just say, "Oh, well this has  
25 got to be all bad," in the situation. Because the

Kelly A. Booth, M.D.,

Page 100

1 chemical foundation or makeup of this device is not to  
2 be used in the human body. So I -- I wouldn't look at  
3 this and say, "Oh, absolutely. I'm not putting any  
4 more TVTs in at all."

5 Q. And from your knowledge of the literature,  
6 is there a well-documented, long and safe use of  
7 polypropylene for the purpose of TVT mesh?

8 A. Yes.

9 Q. And I believe you now have with you a copy  
10 of your CV. Can we mark that?

11 A. Sure. It's a little bit ancient.

12 Q. That is okay. You don't have any reason to  
13 keep it current.

14 A. That is right. Not looking for a new job.

15 Yeah. This is fine. The only thing I say,  
16 the ACOG member. Oh, it's in here. That is okay.  
17 Good. And then strike the AMA. Sorry.

18 Q. That is okay. So you have gone -- gone  
19 ahead and made that change?

20 A. Yes.

21 (Booth Exhibit 8 was marked for  
22 identification.)

23 BY MS. PACKER:

24 Q. So Exhibit 8 is your CV --

25 A. Do you want one of these?